

Date: January 21, 1994 BQC-94-004
To: Rural Health Clinics RHC 1
From: Judy Fryback, Director
Bureau of Quality of Compliance
Subject: Rural Health Clinic (RHC) Laboratory Services/Clinical Laboratory Improvement
Amendments (CLIA) of 1988

Enclosed is a copy of Health Care Financing Administration, Division of Health Standards and Quality Regional Program Letter No. 94-01. The purpose of this letter is to inform you of the revised list of laboratory tests that Rural Health Clinics (RHC) are required to provide directly. Three of the previously required tests have been eliminated. The remaining six required tests, under 42 CFR 491.9, listed in the accompanying Federal Register, are all in the waived category. This permits Rural Health Clinics to operate their laboratories under a Clinical Laboratory Improvement Amendments (CLIA) certificate of waiver.

Rural Health Clinics may elect to perform additional tests which are non-waived, in which case, an appropriate moderate or high complexity certificate must be obtained.

Please share this information with the appropriate staff. Direct any questions you may have to Lois Hess, Hospital and Health Services Section, Bureau of Quality Compliance at (608) 267-1444 or Judy Courtney, Clinical Lab Unit at (608) 266-5753.

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cc: -BQC Staff
-Office of Legal Counsel
-Ann Haney, DOH Admin.
-Kevin Piper, BHCF Dir.
-HCFA, Region V
-Illinois State Agency
-Ohio State Agency
-Michigan State Agency
-Indiana State Agency
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-Non-LTC BQC Memo Subscribers

CLIA
Department of Health & Human Services
105 West Adams Street
Chicago, Illinois 60603

HEALTH CARE FINANCING ADMINISTRATION REGIONAL PROGRAM LETTER NUMBER 94-01

Refer to: CR10

DATE: January 4, 1994

Subject: Rural Health Clinic (RHC) Laboratory Services/Clinical Laboratory Improvement Amendments of 1988 (CLIA)

The purpose of this memorandum is to notify you that a regulation revising the number and complexity of laboratory services an RHC is required to provide directly was published in the Federal Register on December 2, 1993, as a final rule with comment period, and was effective January 3, 1994 (copy attached).

The revised regulation deletes the three laboratory tests (microscopic examination of urine sediment, pinworm test, and gram stain) that RHCs are required to perform that are not in the waived category. Therefore, an RHC will meet the RHC Medicare requirements and applicable CLIA requirements if it obtains a CLIA certificate of waiver, performs only the six laboratory tests using methods that apply to waived tests, and does not perform any tests not waived.

Effective January 3, a CLIA certificate of waiver will not be permitted for any RHC that performs nonwaived tests. An RHC that performs nonwaived tests will be able to participate in the Medicare program only if it obtains the appropriate CLIA certificate and meets the applicable CLIA requirements such as: personnel, quality assurance, patient test management, quality control and proficiency testing as stated in the CLIA regulations that were published in the February 28, 1992, and January 19, 1993, Federal Registers. The proficiency testing requirements are phased in for all previously unregulated laboratories, including RHCs. Beginning January 1, 1994, all RHCs that perform gram stains or any other nonwaived tests (i.e., rapid strep, complete blood counts, infectious mononucleosis screening, or cultures for bacterial identification) must be enrolled in a CLIA-approved proficiency testing program and begin testing proficiency testing samples.

Current determinations regarding compliance with the RHC laboratory services requirement should be based on the new regulation for RHCs (i.e., applied but not yet approved or disapproved).

Please share this information with your CLIA survey staff. If you have any questions, or require additional information, please contact the CLIA Specialist or the Laboratory Consultant for your State.

/s/ Wayne Nelson
CLIA Specialist
Survey & Certification Operations Branch
Division of Health Standards and Quality

/s/ Charles Bennett
Branch Chief
Survey & Certification Operations Branch
Division of Health Standards and Quality

Attachment